

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of MTP's knowledge.

Application:

MTP Medical Technical Promotion GmbH

P.O. Box 4529

d-78510, Tuttlingen

telephone: +49/7461/96630-25

(310) 558-1500

Contact:

James A. Lee

(310) 410-2769

Device Identification:

Common Name:

Suction/Irrigation Tubing Set

<u>Trade Name</u>: (optional)

MTP Laparomat Disposable Tubing Set

<u>Indication</u>: The MTP Laparomat Disposable Tubing Set is intended to be utilized with the Karl Storz Laparomat Universal Laparoscopic Suction/Irrigation Pump to infuse and aspirate sterile irrigation solution into the peritoneal cavity for rinsing or removing carbon deposits, blood clots, or excised tissue during laparoscopic and pelviscopic surgical procedures.

<u>Device Description</u>: The MTP Laparomat Disposable Tubing Set is intended to be utilized with the Karl Storz laparomat Universal Laparoscopic Suction/Irrigation Pump.

<u>Substantial Equivalence</u>: The MTP Laparomat Disposable Tubing Set is substantially equivalent to the predicate devices since the basic features and intended uses are identical.

Signed:

James A. Lee



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL 1 9 2001

MTP Medical Technical Promotion GmbH c/o Mr. James A. Lee, Ph.D. P.O. Box 1954 Culver City, California 90230

Re: K011360

Trade/Device Name: MTP Laparomat Disposable Tubing Set

Regulation Number: 876.1500

Regulatory Class: II Product Code: GCJ Dated: May 2, 2001 Received: May 3, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

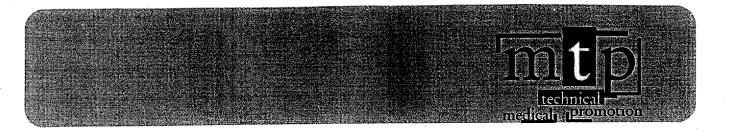
Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure



510(k) Number (if known): K011360

Device Name: MTP Laparomat Disposable Tubing Set

<u>Indication for Use</u>: The MTP Laparomat Disposable Tubing Set is intended to be utilized with the Karl Storz Laparomat Universal Laparoscopic Suction/Irrigation pump to infuse and aspirate sterile irrigation solution into the peritoneal cavity for rinsing or removing carbon deposits, blood clots, or excised tissue during laparoscopic and pelviscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: (Per 21 GFR 801.109)	OR Over-the-Counter Use:
(Division Sign-Off) Division of General, Restorative and New of Rical Devices	(Optional Format 1-2-96)
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